IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM, P.L.C., and BEECHAM GROUP, P.L.C.,	:	CIVIL ACTION
Plaintiffs,	:	
v.	:	NO. 99-4304
APOTEX CORPORATION, APOTEX, INC., and TORPHARM, INC.	:	
Defendants.	:	

MEMORANDUM ON CLAIM CONSTRUCTION

Baylson, J. **March 5, 2010**

I. Introduction

Plaintiffs SmithKline Beecham Corp., Smithkline Beecham, p.l.c., and Beecham Group, p.l.c. (collectively, "GSK"), allege, inter alia, that Apotex Corp., Apotex, Inc., and Torpharm, Inc. (collectively, "Apotex"), infringed upon GSK's United States Patent Number 6,080,759 (filed Sept. 2, 1997) ("'759 Patent"), which "relates to novel compounds, to processes for preparing them and to their use in treating medical disorders." '759 Patent, col. 1, ll. 9-11. In particular, the '759 Patent "provides paroxetine hydrochloride anhydrate substantially free of bound organic solvent." Id., col. 1, ll. 53-55. Presently before the Court are the parties' briefs on claim construction pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir.1995) (en banc), aff'd 517 U.S. 370. (Docket Nos. 497, 499.) On February 24, 2010, the Court heard oral argument on claim construction.

II. Legal Standard

Generally, a claim term is given its "ordinary and customary meaning," that being the definition given by "a person of ordinary skill in the art in question at the time of the invention." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir . 2005) (en banc). The Federal Circuit has explained that the claim construction inquiry begins by looking at the intrinsic evidence: the language of the claims, the specification, and the prosecution history.

"[T]he claims themselves"—that is "the use of a term within the claim," "[o]ther claims of the patent in question, both asserted and asserted," and "[d]ifferences among claims"—"provide substantial guidance as to the meaning of particular claim terms." Id. at 1314. "[I]t is [also] appropriate for a court . . . to rely heavily" on the specification, the patentee's written description, for guidance as to the meaning of the claims." Id. at 1314. In fact, "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Id. at 1315 (quoting Vitrionics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Additionally, the court "should also consider the patent's prosecution history, if it is in evidence." Markman, 52 F.3d at 980. Though "less useful" and "often lack[ing] the clarity of the specification," "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim's scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317.

Apart from intrinsic evidence, the court is also authorized to rely on extrinsic evidence, that being "'evidence external to the patent and prosecution history, including expert and

inventor testimony, dictionaries, and learned treatises.'" Id. (quoting Markman, 52 F.3d at 980). Such evidence, through "shed[ding] useful light on the relevant art," is "less significant than the intrinsic record in determining the legally operative meaning of claim language," and "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Id. at 1317, 1319 (internal quotation marks omitted).

III. Discussion

The parties dispute the construction of several terms relating to the following: (A) "paroxetine hydrochloride anhydrate Form A" ("Form A"); (B) "crystallizing a paroxetine hydrochloride in an organic solvent or a mixture of organic solvents"; (C) "organic solvent not removable by drying"; (D) "displacing the solvent with a displacing agent"; and (E) "a melting point of about 123-125° C."[1]

A. "Paroxetine Hydrochloride Anhydrate Form A"

Claim Term	GSK's Construction	Apotex's Construction
"paroxetine hydrochloride anhydrate Form A"	[no proposed construction]	paroxetine hydrochloride in anhydrate form and having the physical-chemical properties recited in claim 10
"a process to prepare paroxetine hydrochloride anhydrate Form A"	a process to prepare a form of paroxetine hydrochloride anhydrate comprising the following characteristics: a melting point of approximately 123-125°C; IR bands at approximately 513, 538, 571, 592, 613, 665, 722, 761, 783, 806, 818, 839, 888, 906, 924, 947, 966, 982, 1006, 1034, 1068, 1091, 1134, 1194, 1221, 1248, 1286, 1340, 1387, 1493, 1513, 1562, 1604, 3402, and	[no proposed construction]

[1]The parties disagree as to what terms need to be construed. The Court will address all of the disputed terms.

Claim Term	GSK's Construction	Apotex's Construction
	3631 cm-1; a DSC maximum endotherm, measured at 10° C per minute, of approximately 126° C in an open pan and approximately 121° C in a closed pan; characteristic X-ray diffractogram peaks at approximately 6.6, 8.0, 11.2, and 13.1 degrees 2 theta; characteristic solid state 13C-NMR spectrum peaks at approximately 154.3, 149.3, 141.6, and 138.5 ppm, and having solvent of crystallization content less than the amount not removable by conventional drying conditions	

Claim 10 of the '759 Patent, which Claims 11, 14, and 15 incorporate by reference, describes "a process to prepare paroxetine hydrochloride anhydrate Form A." '759 Patent, col. 18, ll. 7-8. Apotex urges the Court to construe only "paroxetine hydrochloride anhydrate Form A" ("Form A") (Apotex Opening 13-14), and GSK contends that the Court should instead construe "a process to prepare" Form A (GSK Opening 9-11).

1. The Parties' Contentions[2]

According to GSK, the parties do not dispute that the construction of Form A terms should recite each of the "characteristics" listed in Claim 10, '759 Patent, col. 18, l. 5, because Form A "was not otherwise known in the pharmaceutical sciences," meaning that "the person of ordinary skill would not understand [it] to have a meaning independent of the definition set out in the '759 Patent." (GSK Opening 10.) GSK avers that Apotex's Opening Construction Brief

[2]The following subsection summarizes only the parties' opening and responsive construction briefs submitted prior to oral argument. The parties' subsequent oral argument and supplemental written submissions are incorporated and summarized when necessary infra in the analysis section. The Court's discussion of the remaining, disputed claim terms follow the same format.

amended an earlier construction that "actually listed several of the analytical characteristics of Form A," by proposing a new construction that only referenced the "properties recited in claim 10," which "does not serve to clarify the meaning of the claim term in a way that will be understandable to the jury, because it does not define what 'properties' it refers to." (GSK Resp. 7.) GSK, initially contended that the intrinsic record indicates that Form A has the "characteristics" listed in Claim 10, and urged the Court to construe the process of preparing Form A by specifying "certain analytical data . . . , including melting point, IR, DSC, X-ray, and C-NMR data." (GSK Opening 10.)

GSK also argues that Claim 10 defines Form A "as having solvent of crystallization content less than the amount not removable by conventional drying conditions,"and that, "by definition, Form A contains less crystallization solvent than the amount not removable by drying." (GSK Opening 11.) GSK contends that the intrinsic record supports an inclusion of comparative crystallization content language in construing Form A. (GSK Opening 12.) According to GSK, the specification and prosecution history indicate that the "applicants . . . understood Form A to be the product of a process that required use of a displacing agent to remove solvent not removable by conventional drying conditions." (GSK Opening 12.) GSK then argues that Apotex's construction "impermissibly omits" that requirement, is "inconsistent with the patent specification[,] and should be rejected." (GSK Opening 12.) As noted below, GSK agreed at oral argument to a simpler cross-reference to Claim 10.

Apotex responds that "[o]ne needn't look further than to claim 10" to understand, and that the parties do not dispute, that Form A has the "specific physical-chemical properties" listed in that claim, and that the intrinsic history indicated that GSK repeatedly explained that these

properties differentiated Form A from "prior-art paroxetine hydrochloride anhydrate." (Apotex Opening 14; see also Apotex Resp. 1.) Apotex further avers that "[t]here is also no dispute that claim 10 is a process claim that requires Form A." (Apotex Resp. 1.) Apotex, however, contends that its construction does not fail to "account for a lower level of crystallization solvent for Form A," but that "Apotex addresses this issue where proper—in its construction of the claim terms 'organic solvent not removable by drying' and 'displacing.'" (Apotex Resp. 1-2.) Apotex therefore urges the Court to adopt its proposed construction.

2. Analysis

The intrinsic evidence plainly provides that Form A has the "characteristics" listed in Claim 10: The specification expressly includes the same embodiments in its description of Form A, see '759 Patent, col. 3, ll. 12-17, and in prosecuting the patent, GSK maintained that the patent itself provided the only definition for Form A, which was not a commonly understood term in the pharmaceutical sciences (see GSK Opening Ex. 12, at GSK 007573332), and distinguished prior art based on Form A's listed "characteristics" (see Apotex Opening Ex. 9, at 4; Ex. 11, at 3-4; & Ex. 15, at 2-3.)

The parties do not dispute that the "characteristics" should be incorporated into the Court's claim construction. In their briefing, the parties contested whether a cross-reference to Claim 10 suffices to explain Form A to the jury; however, at oral argument, GSK's counsel stated that GSK does not believe that the terms relating to Form A need to be construed and does not have a problem with cross-referencing Claim 10. GSK's counsel also represented that it is not necessary to include in the definition language respecting "crystallization content," so long as the construction explained that "Form A is what you get when you follow the steps in Claim 10."

Apotex's counsel then responded that Apotex "agree[s] in principle" to GSK's stance, but still disagrees with the crystallization content language.

The Court has determined that construing Form A by way of a cross-reference to Claim 10 of the Patent is by no means confusing, and that there is no need to restate these characteristics or Claim 10's language respecting crystallization content. At the end of oral argument, the Court suggested that Form A be construed as "paroxetine hydrochloride in anhydrate form, having the 'characteristics' and following the steps recited in Claim 10." The parties did not object to this construction at oral argument, and confirmed in post-argument supplemental letter briefs that they find the Court's tentative construction to be acceptable. (GSK Supp. Br. 1; Apotex Supp. Br. 1.) The Court therefore adopts this construction of Form A. The Court will not construe "a process to prepare" Form A, because the parties do not dispute that Claim 10 describes the Form A preparation process, and GSK proposed only a redundant definition that uses the claim term's own words of "a process to prepare."

B. "Crystallizing a Paroxetine Hydrochloride in an Organic Solvent or a Mixture of Organic Solvents"

Claim Terms	GSK's Construction	Apotex's Construction
"crystallizing a paroxetine hydrochloride in an organic solvent or a mixture of organic solvents"	crystallizing paroxetine hydrochloride in a mixture comprising one or more carbon-based solvents substantially free of water	[no proposed construction]

Claim 10 also provides that the Form A preparation process comprises "crystallizing a paroxetine hydrochloride in an organic solvent or a mixture of organic solvents." '759 Patent, col. 18, ll. 8-11. GSK urges the Court to construe the term (GSK Opening Br. 12-15), and Apotex offers no proposed construction for this term, although it offers a proposed construction

for "organic solvent," words contained within the term now being construed.

1. The Parties' Contentions

GSK argues that "a person with ordinary skill in the art would understand that an organic solvent is a carbon-based solvent," because the claim language and specification provide only carbon-based examples of "organic solvents," and because "organic" is commonly understood to "contain[] carbon compounds." (GSK Opening 13 (internal quotation marks omitted).) GSK also avers that the specification and prosecution history confirm that the invention aimed to provide an anhydrate form of paroxetine hydrochloride, which has "as a preliminary requirement a crystallization medium that is sufficiently free of water such that paroxetine hydrochloride hemihydrate is not produced." (GSK Opening 13-14.) GSK contends that Apotex agrees as to what the claim term means. (GSK Resp. 20.)

Apotex avers that the parties agree that "organic" means "carbon-based," and that an "organic solvent" must be "substantially free of water." (Apotex Resp. 2.) Apotex argues that it "offers that construction where it properly belongs—in discussing the terms "organic solvent," "organic solvents not removable by drying," and "displacing agent." (Apotex Resp. 2.) Apotex contends that GSK's construction fails to address the "critical difference" between "the organic solvent, which must have essentially no water, and the displacing agent, which may be water or, like hydrochloric acid, contain a high percentage of water." (Apotex Resp. 2-3 (internal citations omitted).)

2. Analysis

The Court sees no need to construe the term "crystallizing a paroxetine hydrochloride in an organic solvent or a mixture of organic solvents." GSK's proposed definition defines words

within the term, namely providing that "organic" means "carbon-based" and that "organic solvent" must be "substantially free of water," but otherwise merely recites the words within the term, such as that the term involves "crystallizing paroxetine hydrochloride in a mixture comprising one or more . . . solvents." As described infra, Apotex, which did not propose a construction of this term, only provides a different definition of "organic solvent." As a result, the parties only dispute the definition of "organic solvent," but do not dispute the additional words in the term "crystallizing a paroxetine hydrochloride . . . ." The Court, therefore, will construe the underlying claim term "organic solvent" infra in construing terms relating to "organic solvent not removable by drying," but will not construe "crystallizing a paroxetine hydrochloride in an organic solvent or mixture of organic solvents." (Apotex Opening 19-20; Resp. 3-5)

C. "Organic Solvent Not Removable by Drying"

Claim Term	GSK's Construction	Apotex's Construction
"organic solvent"	[no proposed construction]	the solvent classes defined by the patent specification, and include IPA and acetone
"organic solvent not removable by drying"	[no proposed construction]	
"having organic solvent not removable by drying"	having organic solvent that cannot be removed by conventional drying conditions	[no proposed construction]

Claims 10 and 11 describe the Form A preparation process as comprising an "organic solvent" or mixture of "organic solvents." '759 Patent, col. 18, ll. 9, 10, & 30. Claim 10 also specifies that crystallizing a paroxetine hydrochloride in an organic solvent or mixture of organic solvents, prepares a paroxetine hydrochloride "having organic solvent not removable by drying." Id. col. 18, ll. 11-12. GSK only proposes a definition for "having organic solvent not removable by drying," while Apotex proposes a definition for "organic solvent" and "organic solvent not

removable by drying." (GSK Opening 15-17; Apotex 19-20.)

1. The Parties' Contentions

Although GSK did not propose a definition for "organic solvent," as already explained, GSK incorporated into its definition of "crystallizing a paroxetine hydrochloride in an organic solvent or mixture of organic solvents" understandings that an "organic solvent" is "carbon-based" and "substantially free of water." (GSK Opening 12-15.) As for its proposed construction for "having organic solvent that cannot be removed by conventional drying conditions," GSK contends that both the specification and the prosecution history explain that "not removable by drying" means not removable under "conventional drying conditions." (GSK Opening 15-17.) According to GSK, Apotex's construction imports unnecessary and restrictive limitations, that is, the examples of IPA and acetone, into the claims. (GSK Resp. 21-32.)

Apotex responds that Claims 2 and 11, and the specification, include IPA, which includes "propan-2-ol," and acetone in the group of "organic solvent[s] not removable by drying." (Apotex Opening 19-20.) Apotex continues that it does not seek to limit the definition to only IPA and acetone, but rather, to explain to the jury that these are the only two organic solvents relevant to the present case. (Apotex Resp. 4.) Moreover, Apotex contends that organic solvents and displacing agents do not possess the same characteristics, and that because IPA and acetone are listed as organic solvents in the patent, they supposedly cannot be displacing agents. (Apotex Resp. 4.) Apotex then argues that it is not possible, using drying, to reduce the level of bound organic solvent to less than two percent, meaning that two percent is the dividing line between the solvate and the anhydrate. (Apotex Opening 19-20.) Apotex criticizes GSK's construction as being unhelpful and repetitive, given that the parties agree that "the organic solvent is not

removable (from the crystal lattice) by drying." (Apotex Resp. 3.)

2. Analysis

The Court will address the terms "organic solvent" and "organic solvent not removable by drying" in turn. The Court will not construe "having organic solvent not removable by drying," because there is no dispute as to what "having" means, the dispute as to the rest of the term will be resolved by construing "organic solvent not removable by drying." GSK merely reuses the word "having" in its proposed construction as "having organic solvent."

. **(i) "Organic Solvent"**

Turning first to "organic solvent," the intrinsic record indicates, and the parties agree (GSK Opening 13-14; Apotex Resp. 2), that "organic" means "carbon-based" and that the "solvent" referenced in the '759 Patent is "substantially free of water." As to "organic," Claim 11 lists several organic solvents that may be used to crystallize Form A, all of which are carbon-based, as does the specification.[3] Moreover, "organic" is defined in Merriam-Webster's Collegiate Dictionary as being "of, relating to, or containing carbon compounds," Merriam-Webster's Collegiate Dictionary 819 (10th ed. 1995). As for "solvent," the specification provides that "[t]he organic solvents should be substantially free of water," '759 Patent, col. 5, l. 58, and that the only water that the invention can contain is "unbound water that is to say water which is other than the water of crystallization," id. col. 2, ll. 38-39. A declaration submitted by Dr. George Wellman during the prosecution of the parent patent application (08/733.874)

[3]In particular, Claim 11 lists "propan-2-ol, propan-1-ol, ethanol, acetic acid, pyridine, acetonitrile, acetone, tetrahydrofuran, [and] chloroform," '759 Patent, col. 18, ll. 27-30, and the specification provides "alcohols especially alkanols such as propan-2-ol, ethanol and propan-1-ol; organic acids such as acetic acid; organic bases such as pyridine; nitrites such as acetonitrile; ketones such as acetone; ethers such as tetrahydrofuran and chlorinated hydrocarbons such as chloroform," id. col. 5, ll. 10-14, as examples of organic solvents for purposes of the '759 Patent.

differentiated the invention from prior art that "inevitably resulted in the production of hemi-hydrate," and therefore, failed to be substantially free of water. (GSK's Opening, Ex. 12, at GSK00757301.)[4]

The Court turns next to Apotex's argument that "organic solvent" should be construed to specifically list as examples IPA and acetone. In Phillips, the Federal Circuit explained that "although the specification often describes very specific embodiments of the invention, [the court] ha[s] repeatedly warned against confining the claims to those embodiments." 415 F.3d at 1323. Here, Apotex does not seek to restrict "organic solvent" to only IPA and acetone, and therefore, is not proposing a construction that runs afoul of Phillips' teaching respecting reading limitations into the patent. Nonetheless, the inclusion of those two solvents in the construction of "organic solvent"is unwarranted because doing so would interfere with the factfinder's right to decide the factual question of which particular solvents in the accused product and prior art fall within the claim limitations. The Federal Circuit has clarified that "a court, under the rubric of claim construction, may [not] give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product," PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998), nor is it appropriate at the Markman stage to determine how the claim terms apply to the "accused device to determine infringement," SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1118 (Fed. Cir. 1985). The Court, therefore, will construe "organic solvent" to be "carbon-based solvent that is substantially

[4]In its supplemental brief, Apotex contends that "the construction limits . . . carbon-based solvents to organic solvents substantially free of water," and therefore proposes that the construction of the term "crystallizing a paroxetine hydrochloride in an organic solvent or mixture of organic solvents" to be "crystallizing paroxetine hydrochloride in one or more organic carbon-based solvents that are substantially free of water." (Apotex Supp. Br. 2.) The Court declines to add the word "organic" in its construction of "organic solvent," because doing so would be redundant, and the word "organic" seems to mean "carbon-based."

free of water."

(ii) "Organic Solvent Not Removable by Drying"

As a preliminary matter, the Court will not construe "organic solvent not removable by drying" to be the same as "organic solvent." Apotex urges the Court to do so under the rationale that the terms are "used interchangeably in claim 10." (Apotex Supp. Br. 2.) The Court disagrees, because the Claim first uses the word "organic solvent" to identify where the crystallization process occurs, '759 Patent, col. 18, ll. 8-11, and then goes on to explain that the process prepares "a paroxetine hydrochloride having organic solvent not removable by drying," id. col. 18, ll. 11-12, thereby using the terms in different ways.

As for the proper construction of "organic solvent not removable by drying," the specification states that "[s]ubstantially free of bound organic solvent is to be interpreted to be less than the amount . . . which would remain . . . bound . . . under conventional vacuum oven drying conditions." '759 Patent, col. 1, ll. 62-63. The specification then provides that the product is "dried by conventional methods such as drying in vacuo" before the displacing agent is applied to remove further solvent. Id. col. 5, ll. 15-22. As a result, the specification, which is the "single best guide to the meaning of a disputed term,'" Phillips, 415 F.3d at 1315, indicates that the inventors intended for "drying" to refer to "conventional" vacuum oven drying conditions, thereby supporting GSK's proposed construction. The prosecution supports this definition by providing that the inventors "managed to prepare paroxetine hydrochloride anhydrate . . . which was so tightly bound that [organic solvent] could not be removed by conventional drying conditions." (GSK Opening Ex. 12 at GSK 00757301.)

In addition, the Court does not take into account Apotex's contention that two percent is

the dividing line between the solvate and anhydrate (Apotex Opening 19-20), because neither the specification nor the claim language refer to the two percent cutoff. In addition, Apotex did not include this two percent cutoff in its proposed definition, or otherwise explain how this affects the construction of the disputed claim term, such as by showing that the process covered by the '759 Patent does not require the removal of more organic solvent than can be removed by conventional drying alone. Thus, the Court will not include any reference to the two percent. The Court will construe "organic solvent not removable by drying" as "having organic solvent that cannot be removed by conventional drying conditions."

D. "Displacing the Solvent with a Displacing Agent"

Claim Term	GSK's Construction	Apotex's Construction
"displacing" or "displaced"	[no proposed construction]	using a "displacing agent" to remove from the crystal bound "organic solvent not removable by drying" in order to obtain paroxetine hydrochloride anhydrate that could not be obtained by drying alone
"displacing agent"	[no proposed construction]	water, supercritical CO2, and hydrochloric acid
"displacing the solvent with a displacing agent"	contacting the paroxetine hydrochloride having organic solvent not removable by conventional drying conditions with an agent to permit reduction of the solvent content to less than the amount not removable by conventional drying conditions	[no proposed construction]

Claims 10, 11, 14, and 15 describe the Form A preparation process as involving "displacing" of the solvent, '759 Patent, col. 18, ll. 13, 30, 39, & 41, Claims 10 and 11 provide that the process uses a "displacing agent," id. col. 18, ll. 13, 31, and Claims 10 and 11 describe the process as "displacing the solvent with a displacing agent," id. col. 18, ll. 13, 30-31. Apotex

urges the Court to construe "displacing agent" and "displacing," while GSK proposes a construction for "displacing the solvent with a displacing agent." (GSK Opening Br. 17-21; Apotex Opening Br. 20-31.)

1. The Parties' Contentions

According to GSK, Claim 10 involves a two-step procedure—"first, crystallizing paroxetine hydrochloride that has solvent not removable by drying; and second, displacing the solvent with a displacing agent"—and the disputed claim terms relate to the second step. (GSK Opening 18.) GSK contends that the specification repeatedly describes the displacing process as "contacting" the paroxetine hydrochloride with the displacing agent, and teaches that the crystallization product has been conventionally dried before such contact takes place, and that after the contact, the use of additional drying displaces the solvent. (GSK Opening 18.) GSK argues that the specification thereby shows that the displacing agent alone does not remove the solvent, but that removal is accomplished through a combination of contact and drying. (GSK Resp. 33-35.) GSK continues that Apotex ignores this and reads out of the specification the conventional drying aspects, by proposing a construction whereby the displacing agent actively "removes" the bound solvent. (GSK Resp. 35.)

GSK also takes issue with Apotex's construction that "displacing agent" is limited to water, supercritical carbon dioxide, and hydrochloric acid. (GSK Opening 18-19; GSK Resp. 33-35.) GSK avers that the specification expressly leaves open the possibility that other displacing agents may be selected by way of routine experimentation, that the intrinsic evidence did not suggest that the applicants only contemplated the three listed displacing agents, and that it is contrary to Federal Circuit precedent to limit the specification to the listed embodiments. (GSK

Opening 19.) To the extent that Apotex's construction suggests that organic solvents cannot be displacing agents, GSK contends that "the specification contains no teaching" to this effect. (GSK Opening 19 (emphasis removed).)

Apotex responds that the intrinsic evidence demonstrates that drying cannot be a part of the "displacing" step, because the applicants represented that conventional drying alone did not remove the solvent bound inside the crystal, but that "the 'displacing agent' is the actor solely responsible for 'displacing' the bound solvent." (Apotex Resp. 14.) Apotex therefore contends that "removes" rather than "contacts" is the proper verb to use in construing "displacing" for purposes of the '759 Patent. (Apotex Resp. 14-15.)

Apotex also contends that it is necessary to limit the construction of "displacing agent" to the three listed in the specification, because there is no ordinary meaning of the claim term, and the three listed agents have no common properties that would permit the discovery of additional displacing agents through routine experimentation. (Apotex Resp. 6-8.) Apotex continues that notwithstanding the specification's language indicating that other displacing agents might exist, the specification also indicates that using a different "displacing agent" could lead to an undesired result, and that in prosecuting the patent, the inventors indicated that they did not contemplate additional displacing agents. (Apotex Opening 20-23.) Apotex further avers that as an English Court of Appeals found under a counterpart to the '759 Patent , an "organic solvent not removable by drying" is not a "displacing agent," and thus, the organic solvent acetone cannot itself be a displacing agent. (Apotex Opening 24-28.) Apotex then contends that adopting GSK's broad construction would run afoul of Section 112's specificity and enablement provisions by not explaining to those skilled in the art how to identify additional displacing

agents. (Apotex Opening 28-31.) Apotex concludes that its proposed constructions are supported by the record and thus should be adopted.

2. Analysis

The parties' proposed constructions present two primary disputes: (1) whether "displacing agent" should be limited to the three listed in the patent; and (2) whether the displacing agent actively removes the organic solvent from the paroxetine hydrochloride or merely facilities this removal.

For the first question, the parties do not dispute, and the Court finds, that there are only three "displacing agents" identified in the patent specification: water, see '759 Patent, col. 5, ll. 21-22, 25-34; id. col. 9, l. 35 (Example 4), supercritical carbon dioxide, see id. col. 5, ll. 21-22, 48-54, and hydrochloric acid, see id. col. 9, l. 33 (Example 4); id. col. 10, l. 4 (Example 5).

The specification, however, also expressly states, "It is possible to use other displacing agents which may be selected by means of routine experimentation." Id. col. 5, ll. 22-24. The Phillips court made clear that the construction of a claim term should not be restricted to the patent's preferred embodiments, thereby reading in unnecessary and unintended limitations. 415 F.3d at 1323. Here, the Court does not view the prosecution history as showing that the inventors conceded that they could not conceive of additional "displacing agents."

Apotex points to several declarations filed with the Patent and Trademark Office (PTO) that purportedly demonstrate that the inventors do not conceive of other possible "displacing agents" for purposes of the '759 Patent. In particular, Dr. Victor Jacewicz, one of the inventors, stated that he could not reproduce prior art methods for making paroxetine hydrochloride anhydrate and that using water, "[u]nexpectedly," he "found a procedure by which it was possible

to displace . . . as described in the present application despite the fact that vigorous vacuum drying was ineffective." (Apotex Opening Ex. 19, at 4.) Jacewicz's boss, Dr. Wellman, then remarked that "the fact that this solvent could be displaced by water, without causing conversion to . . . hemi-hydrate was particularly unexpected," and that he was "very surprised" that tightly bound propan-2-ol could be removed "using an agent such as water or supercritical carbon dioxide." (Apotex Opening Ex. 20, at ¶ 7.) Professor Joel Bernstein, a crystallography and polymorphism expert, expressed similar "surprise," and further stated, "I cannot think of another way over and above what is described in the present application, which could reasonably expect to be successful, of preparing paroxetine hydrochloride anhydrate substantially free of bound solvent." (Apotex Opening Ex. 21, at ¶ 9.) Apotex essentially asks this Court to find that GSK disclaimed coverage of "displacing agents" not listed in the specification.

"The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution." Omega Eng'g, Inc, v. Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003). "[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." Id. at 1325. The Federal Circuit, however, requires statements to be "both so clear as to show reasonable and deliberateness" and "so unmistakable as to be unambiguous evidence of disclaimer" before applying the doctrine. Id. at 1325; see also id. at 1324-25 (describing and comparing cases involving an ambiguous claim disavowal with those involving a clear disavowal). Such a requirement aims "[t]o balance the importance of public notice with the right of patentees to seek broad patent coverage." Id. at 1325.

Jacewicz, Wellman, and Bernstein's comments fall short of constituting unequivocal disavowal: The statements only indicate that the invention was novel and surprising given prior art methods for making paroxetine hydrochloride anhydrate. While Bernstein's comments come the closest to suggesting that he does not contemplate other "displacing agents," he never expressly states this, remarking only that he cannot think of "another way over and above what is described in the present application" (Apotex Opening Ex. 21, at ¶ 9), an application that expressly left open the possibility that other "displacing agents" could be discovered through routine experimentation. Dr. Bernstein never stated that routine experimentation could not lead to the discovery of additional "displacing agents." '749 Patent, col. 5, ll. 22-24. Prosecution disclaimer, therefore, does not apply, and the Court will not limit the definition of "displacing agent" to those identified in the patent specification.[5]

Turning next to the question of the role displacing agents play in removing organic solvent, the patent specification repeatedly uses the word "contact" to describe the interaction the displacing agents have with the paroxetine hydrochloride during displacement.[6] The patent

[5]The Court declines to come to a contrary result based on foreign court decisions regarding foreign counterparts to American patents, because the Federal Circuit has cautioned against doing so, and because the intrinsic record supports GSK's construction. See Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc., 21 F.3d 1068, 1072 n.2 (Fed Cir. 1994) ("We take notice of the fact that the theories and laws of patentability vary from country to country, as do examination practices. Caution is required when applying the action of a foreign patent examiner to deciding whether the requirements of 35 U.S.C. § 103 are met under United States law, for international uniformity in theory and practice has not been achieved.")

[6]See '759 Patent, col. 5, ll. 26-27 ("It is important that the paroxetine hydrochloride solvate is contacted with enough water . . . .") (emphasis added); id. col. 5, ll. 30-33 ("The amount of water, the form of the water, . . . and the length of time which the paroxetine hydrochloride solvate is contacted with the water differs from solvate to solvate.") (emphasis added); id. col. 5, ll. 44-46 ("After contact with water to displace the bound solvent, the product is suitably dried." (emphasis added).

specification then teaches that after such "contact," drying takes place to remove the organic solvent.[7] At oral argument, Apotex, with the help of a computer animation video purportedly illustrating the displacement process, asserted that the displacing agent removes organic solvent from the paroxetine hydrochloride's crystal structure, and that subsequent drying then removed that solvent from the overall structure.

The Court declines to determine at this stage whether Apotex and its intrinsic evidence correctly characterize the exact removal process, or whether "contacting" and "drying" are two separate steps, as GSK contends (GSK Resp. 34-40), because the intrinsic record does not support Apotex's construction. The Court has not found language in the patent or subsequent prosecution history indicating that the displacing agents actively remove organic solvent from the paroxetine hydrochloride's crystal structure, nor has Apotex identified any such language. Instead, as already detailed, the intrinsic evidence shows that the displacing agent's contact with the paroxetine hydrochloride is followed by drying, which results in removal of organic solvent. The Court declines to add "precision or specificity" to the claim terms respecting the displacing process that the patent itself lacks. PPG Indus., 156 F.3d at 1355. The Court notes that its construction of displacing as permitting the removal of bound organic solvent does not preclude Apotex from presenting evidence on how active of a role the displacing agent plays in removing organic solvent at trial.

Consistent with the determinations described above, the Court will construe "displacing"

[7] See '759 Patent, col. 5, ll. 44-46 ("After contact with water to displace the bound solvent the product is suitably dried, for example, in vacuo at elevated temperature."). Several Examples in the specification involved drying following contact with the displacing agent. See id. col. 8, ll. 4-8 (Example 1); id. col. 9, ll. 31-35 (Example 4); id. col. 10, ll. 3-7 (Example 5); id. col. 10, ll. 36-40 (Example 5); id. col. 12, ll. 23-25 (Example 9); id. col. 12, ll. 59-62 (Example 10); id. col. 13, ll. 27-29 (Example 11); id. col. 14, ll. 14-16 (Example 13); id. col. 15, ll. 9-11 (Example 15).

to be "contacting to permit reduction of," "displaced" to be "contacted to permit reduction of," and "displacing agent" to be "agent permitting reduction of solvent to obtain paroxetine hydrochloride anhydrate that cannot be obtained by drying alone," and "displacing the solvent with a displacing agent" to be "contacting the paroxetine hydrochloride with a displacing agent to permit reduction of the solvent to obtain paroxetine hydrochloride anhydrate that cannot be obtained by drying alone."

E. "A Melting Point of About 123-125º C"

Claim Term	GSK's Construction	Apotex's Construction
"a melting point of about 123-125º C"	an end of melting of approximately 123-125º C	temperature at which paroxetine hydrochloride anhydrate Form A is at equilibrium between the solid and liquid phases, as determined using a capillary melting point apparatus, where that temperature is between 123±1º C and 125±1ºC, with the word "about" accounting for any experimental error in the measurement

Claim 10 describes Form A as having "a melting point of about 123-125º C," '759 Patent, col. 18, ll. 15-16, and the parties dispute how to construe this term.

1. The Parties' Contentions

GSK avers that the specification, although not providing a definition of "melting point," indicates that the term should be construed with reference to the pharmaceutical field, because the invention relates to pharmaceuticals. (GSK Opening 21.) GSK contends that the United States Pharmacopeia (USP) is "the authoritative pharmaceutical reference relied upon by both parties' experts." (GSK Resp. 7.) According to GSK, the USP confirms that the melting point is the temperature at which a test substance fully becomes liquid, thereby supporting GSK's

construction. (GSK Resp. 7-8.) GSK argues that Apotex's construction draws support from "generalized organic chemistry" publications, rather than from pharmaceutical texts. (GSK Resp. 9-10.)

As for the word "about" in the disputed claim term, GSK argues that case law has construed the word to mean "approximately," without requiring additional specificity or details. (GSK Resp. 14-16.) GSK contends that Apotex itself previously proposed the same definition, and that the prosecution history indicates that the inventors intended for the term to account for the practical variation associated with measuring the melting point. (GSK Resp. 14-16.) GSK continues that there is no intrinsic evidence supporting Apotex's assertion that experimental variation is up to a degree, and that Apotex, in essence, seeks to have the Court weigh in on a contested infringement issue regarding how to define the range of "about 123 to 125 degrees." (GSK Resp. 16-19.)

Apotex, however, contends that several prior art references, including a text authored by one of GSK's experts, define melting point as the temperature when a compound is in equilibrium between its liquid and solid phases or forms, and that a person of ordinary skill in the art would not understand the melting point to be when a compound has finished melting. (Apotex Opening 15-16; Apotex Resp. 16-17.) According to Apotex, "melting point" relates to thermal properties and should be measured using a capillary apparatus. (Apotex Opening 16.)

As for the temperature range described in the disputed claim term, Apotex avers that Federal Circuit cases have clarified that "about" is "notorious" for its vagueness and is dependent upon the factual situation presented. (Apotex Resp. 16.) Apotex continues that here, "about" refers to the range of experimental error associated with determining the melting point using a

capillary apparatus, and that a person with ordinary skill in the art would understand that each analytical technique has its own degree of precision. (Apotex Resp. 17.)

2. Analysis

First of all, "melting point" should be construed in the context of pharmaceutical products, because the specification indicates that the invention covered by the '759 Patent "relates to novel compounds, to processes for preparing them and to their use in treating medical disorders, id. col. 6, ll. 9-11, and is used in various "pharmaceutical compositions," id. col. 7, ll. 1-42. In construing "melting point," the primary issues disputed by the parties are as follows: (1) whether the "melting point" is the "end of melting" or the temperature at which the substance is at an "equilibrium between the liquid and solid states"; (2) whether the method of measuring the melting point, such as use of a "capillary melting point apparatus," needs to be specified; (3) whether "about" means "approximately" or needs to also account for "experimental error"; and (4) whether the temperature range needs to be specified with a variation of give or take a degree.

Turning first to the proper construction of "melting point," neither party points to any intrinsic evidence shedding light on the inventors' understanding of the term, nor has the Court found any. The Court, therefore, will look to extrinsic evidence to define "melting point," which may "shed useful light on the relevant art." Phillips, 415 F.3d at 1317. Merriam-Webster's Collegiate Dictionary defines "melting point" as "the temperature at which a solid melts." Merriam-Webster's Collegiate Dictionary 723 (10th ed. 1995). The USP, upon which GSK relies and which the parties' experts accept as a standard pharmaceutical text,[8] explains that "the melting range or temperature of a solid is defined as those points of temperature within which, or

[8](See GSK Opening, Ex. 3A (Byrn Rep.), at ¶¶ 40-41; GSK Opening, Ex. 3B (Byrn Opp. Rep.), at ¶ 26; GSK Opening, Ex. 14, at ¶¶ 63-64 (Mislow Rep.).)

at the point which, the solid coalesces and is completely melted," and that "the temperature at which the test substance becomes liquid throughout is defined as the end of melting or the 'melting point.'" The United States Pharmacopeia, The National Formulary 1805 (1995).

The USP's definition is supported by the European Pharmacopoeia, the European counterpart to the USP, which defines the "melting point determined by the capillary method [a]s the temperature at which the last solid particle . . . passes into the liquid phase." European Pharmacopoeia 23 (3d ed. Council of Europe 1996). Dr. Kurt Mislow, one of Apotex's experts, also noted in his thesis that the melting point "is readily determined at the disappearance of the last crystal. (GSK Opening Ex. 24, at 55.) Thus, learned pharmaceutical texts understand melting point to be the temperature at which a solid becomes a liquid. The Court, however, will not adopt GSK's proposed "end of melting" language, because this adds confusion by suggesting that "melting point" is a temporal measure, rather than a temperature point.

Apotex seeks to have melting point construed in terms of the temperature at which an equilibrium exists between the solid and liquid states, and cites to several texts so defining the term.[9] The Court declines to adopt a similar construction. Most of the sources relied upon by Apotex are organic chemistry texts, rather than treatises specific to the pharmaceutical sciences, which is the relevant context for purposes of the '759 Patent, as this Court has already explained.

[9]See Solomons, Organic Chemistry 76 ("The melting point of a substance is the temperature at which an equilibrium exists between the well-ordered crystalline state and the more random liquid state."); Joel Bernstein, Polymorphism in Molecular Crystals 40 (Oxford Univ. Press 2002) ("The melting point is defined as the temperature at which the liquid is in equilibrium with the solid . . . ."); Douglas C. Neckers & Michael P. Doyle, Organic Chemistry 11 (John Wiley & Sons 1977) ("The melting point of any substance is the temperature at which the solid and liquid phases of that substance exist in equilibrium." (emphasis removed); C. David Gutsche & Daniel J. Pasto, Fundamentals of Organic Chemistry 135 (Prentice-Hall, Inc. 1975) ("The melting point . . . is the temperature at which the solid and liquid phase are in equilibrium.").

More importantly, the Court finds Apotex's proposed construction to be unnecessarily detailed and confusing. As the texts cited by Apotex demonstrate, defining "melting point" in terms of equilibrium focuses on the intermolecular forces and thermal energy between the particles, and the energy needed to bring about the transformation of the solid into the liquid.[10] These definitions in no way contradict the USP's definition and instead describe melting point on a molecular and chemical level. In fact, one of the organic chemistry texts relied upon by Apotex expressly confirms that the two sets of definitions are not incongruous by first defining melting point in terms of being an equilibrium, and then stating that "[t]he temperature at which a crystalline solid changes to a liquid or melts, is called the melting point." Solomons, supra note 8, at 425 (emphasis removed). Apotex's construction also lacks intrinsic support, because Claim 10 of the '759 Patent only uses the disputed melting point term in order to describe the analytical characteristics embodied by Form A, rather than detailing what happens at the chemical and molecular level when Form A melts. The Court, therefore, has determined that the appropriate definition of melting point for purposes of the present invention is the temperature at which a solid becomes a liquid. The Court finds that this definition will be understandable and helpful to the trier of fact.

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[10]See Solomons, supra note 8, at 76 ("A large amount of thermal energy is required to break up the orderly structure of the crystal into the disorderly open structure of a liquid."); Bernstein, supra note 8, at 40 ("The melting point is defined as tthe temperature at which the liquid is in equilibrium with the solid so that the difference in Gibbs free energy between the two phases is zero); Neckers & Doyle, supra note 8, at 11 ("When melting occurs the regular arrangement in the crystalline lattice becomes the random array of particles of the liquid. Such a transformation requires the addition of sufficient kinetic energy, usually in the form of heat, to break down the crystal lattice."); C. Gutsche & Pasto, supra note 8, at 135 ("The melting point . . . of a substance can be defined as the temperature at which the thermal energy of the particles driving them apart from each other is equal to the intermoleular forces holding them together in the solid state.)

Regarding whether to include in the construction the "capillary . . . apparatus," the Court has not found, nor has Apotex identified, anything in the intrinsic evidence indicating the appropriate method for measuring the melting point. Because the Federal Circuit clarified that "a court, under the rubric of claim construction, may [not] give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product," PPG Indus., 156 F.3d at 1355, this Court will not include language respecting "capillary . . . apparatus" in its construction of the melting point claim term.

As for the word "about," numerous Courts have construed "about" to mean "approximately" in cases in which the intrinsic evidence did not demonstrate that the inventor intended for the word to have a specific meaning, [11] For example, in Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364 (Fed. Cir. 2005), the parties disputed how to construe "about" in relation to a claim term respecting dosage. The Federal Circuit held that the inventor "did not clearly set out its own definition of 'about' with reasonable clarity, deliberateness, and precision, and thus failed to act as its own lexicographer." Id. at 1371 (internal quotation marks omitted). The Merck court then concluded that because "the specification . . . suggest[ed] the patentee contemplated a range of dosages," "the term 'about' should be given its ordinary and accepted meaning of 'approximately.'" Id. at 1372. The same is true in this case. The language of Claim 10 demonstrates that the inventors contemplated a range of temperatures, from 123

[11] See, e.g., Merck & Co., Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1367-72 (Fed. Cir. 2005); ACCO Brands USA LLC v. Secucomputer, Inc., No. 03-1820, 2008 WL 2566863, at *3 (N.D. Ill. June 25, 2008); Roche Diagnostics Operations, Inc. v. Abbott Diabetes Care, No. 07-0753, 2009 WL 2973165, at *9 (D. Del. Sept. 15, 2009); Biopolymer Eng'g, Inc. v. Immunocorp., No. 05-0536, 2007 WL 4562592, at *11-12 (D. Minn. Dec. 21, 2007); Kim v. Dawn Food Prods., No. 01-1906, 2004 WL 2658068, at *4-5 (N.D. Ill. Oct. 13, 2004); Cellnet Data Sys., Inc. v. Itron, Inc., 17 F. Supp. 2d 1100, 1114 (N.D. Cal. 1998).

degrees to 125 degrees Celsius. No other definition of "about" is set out in the specification or any other part of the intrinsic record. The Court, therefore, sees no reason to depart from the ordinary meaning of the word "about."[12]

Turning finally to the temperature range, nothing in the intrinsic record appears to support Apotex's assertion that temperature measurements vary up to a degree, and Apotex's briefing are noticeably silent as to the reasons for adopting such a construction. Not only is this Court reluctant to adopt a construction that imports "additional precision or specificity" not present in the patent itself, PPG Indus., 156 F.3d at 1355, but also, the Federal Circuit does not require "mathematical precision" in a patentee's definition of his invention. Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1340-41 (Fed. Cir. 2003). As with the "capillary . . . apparatus" language Apotex seeks to read into the construction, the Court has determined that it is not necessary to include the range of purported temperature measurement variation in construing "melting point." In accordance with the reasons detailed above, the Court construes "a melting point of about 123-125º C," to be "the temperature at which the solid becomes a liquid, of approximately 123-125º C."

IV. Conclusion

The Court will construe the terms in the '759 Patent consistent with the above analysis. An appropriate Order follows.

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[12]A contrary result is not warranted by BJ Services v. Halliburton Energy Services, Inc., 338 F.3d 1368, 1372-73 (Fed. Cir. 2003), in which the patentee "argue[d] that the term "about" [wa]s intended to encompass the range of experimental error that occurs in any measurement." BJ Services did not focus on claim construction, and instead examined whether the claim term met the definiteness requirement. See id. BJ Services, therefore, is inapposite.